AF/3739

P&G Case 8431M

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of	:	
Vladimir Gartstein et al.	:	Confirmation No. 4983
Serial No. 10/078,043	:	Group Art Unit 3739
Filed February 19, 2002	:	Examiner Michael F. Peffley

For Method And Apparatus For The In-Vivo Treatment Of Pathogens

BRIEF ON APPEAL

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed, pursuant to 37 C.F.R. 1.192(a), is Appellant's brief on Appeal for the above application. The Brief is being forwarded in triplicate.

The fee for this Brief on Appeal is $330.00 37 CFR 1.17(c).

The Director is hereby authorized to charge the above fee, or any additional fees that may be required, or credit any overpayment to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

By _____
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Date: June 1, 2004

Customer No. 27752

(BriefonAppealTrans.doc)
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Vladimir Gartstein et al.	: Group Art Unit: 3739
Serial No. 10/078,043	: Examiner: Michael F. Peffley
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For: Method And Apparatus For The In-Vivo Treatment Of Pathogens

The Assistant Commissioner for Patents
Washington, DC 20231

APPEAL BRIEF

Dear Sir:

Enclosed are triplicate copies of Appellant's Appeal Brief. The authorization to charge the fee for filing this Brief was provided with the Notice of Appeal.

1. Real Party in Interest

The real party in interest is The Procter & Gamble Company.

2. Related Appeals and Interferences

None known.

3. Status of Claims

Claims 1-13 are finally rejected under 35 U.S.C. 102, 103 and appealed.

4. Status of Amendments

Amendments were made after Final Rejection and entered.

5. Summary of the Invention

Appellants' claimed invention (see claim 1 which is representative) relates to an apparatus and a method for accomplishing meaningful suppression of the growth potential of a pathogen *in-vivo*. (page 9, line 22-25). The *in-vivo* location may be the "interior or inside of a living organism," or the inner ear of an organism, wherein the term "organism" includes plants. (page 6, lines 8-12; page 7, lines 13-15; page 20, lines 6-7).

The apparatus (Fig. 1, item 30, Fig. 2, item 30, Fig. 3, item 70; Fig. 4, item 80) of the present invention utilizes an electromagnetic radiation source (Fig. 2, item 55, Fig. 3, item 55'; Fig. 4, item 120) which provides electromagnetic radiation at a sufficient intensity to achieve meaningful suppression of the growth potential of the pathogen. (page 9, lines 24-29). The electromagnetic radiation source is capable of providing broad-spectrum electromagnetic radiation having wavelengths ranging from about 190 nm to 1200 nm, and at least part of the apparatus is adaptable to be placed proximate to the *in-vivo* location of the pathogen. (Fig. 1, item 10; Fig. 2, item 10; Fig. 3, item 10'; Fig. 4, item 110; page 9, lines 4-5, 8-9, 13-14, 20-21, and 25-27).

In one specific embodiment, at least part of the apparatus is "especially adapted for the reduction of pathogens in the auditory system of a mammal." (page 20, lines 24-25). As an example, the apparatus could be used to treat "inner ear infections such as acute otitis media." (page 20, lines 25-27). In this embodiment, at least a portion of the apparatus is adaptable for placement proximate to a tympanic membrane of an animal. (*See* page 20, lines 24-31; page 21, lines 1-5). The electromagnetic radiation intensity is such that it provides a meaningful suppression of the growth potential for acute otitis media while minimizing erythema[1] on the tympanic membrane of said animal. (page 21, lines 1-5).

The method of the present invention achieves the meaningful suppression of the growth potential of a pathogen in a living organism. (page 21, lines 19-20). Utilizing the apparatus of the embodiment described above, the electromagnetic radiation is applied to a living organism at the locus of the pathogen within the organism. (page 21, lines 21-23).

6. Issues

Are claims 1-13 anticipated under 35 U.S.C. §102 over U.S. Patent No. 5,720,772 issued to Eckhouse?

Is claim 10 obvious under 35 U.S.C. § 103 over U.S. Patent No. 5,720,772 issued to Eckhouse in view of U.S. Patent No. 5,344,433 issued to Talmore?

7. Grouping of Claims

The claims stand or fall together.

8. Arguments

[1] Exposure of the skin to electromagnetic radiation may cause acute tissue effects on or near locus of the pathogen which are temporary in nature, and typically include, erythema, redness, swelling, scaling and/or inflammation. (page 11, lines 3-8).

I. The Final Office Action fails to properly reject claims 1 or 11 under 35 U.S.C. § 102 as anticipated by Eckhouse because Eckhouse does not teach all of the claim elements of claim 1 or claim 11.

The Final Office Action rejects claims 1-13 under 35 U.S.C. § 102 as anticipated by Eckhouse. Contrary to the Examiner's position, however, these rejections are improper and should be reversed because the cited reference fails to teach or disclose all of the claim elements of claim 1 or claim 11.

A. Functional language of claim 1 constitutes a structural limitation which is not taught in the Eckhouse reference.

Appellants responded to a first office action on December 1, 2003 asserting that the Eckhouse reference did not teach an apparatus that "is adapted for placement proximate to the *in-vivo* location of said pathogen, wherein said *in-vivo* location of said pathogen is a plant or parts thereof" as recited, in part, by claim 1. In response to the arguments of the Appellants, the Final Office Action states that "the added limitation is merely directed towards the intended use of the device and is no way a structural limitation." (page 4-5, line 22 and 1-2). The Final Office Action then concludes that "there is no 'element' missing from the Eckhouse reference as Eckhouse teaches every structural element and is simply silent with respect to the use of the device to treat a plant." (page 5, lines 2-4).

However, it has been held that a functional limitation in a claim "must be evaluated and considered... for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." (MPEP §2173.05(g)). Claims containing language such as "members adapted to be positioned" provide structural attributes to a claimed assembly. (*See* MPEP § 2173.05(g) citing *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976)).

Appellants assert that the limitation of claim 1 does in fact add structural limitations to the claim in that the apparatus is "**adapted** for placement proximate to the *in-vivo* location of said pathogen, wherein said *in-vivo* location of said pathogen is a plant or parts thereof." (See claim 1)(emphasis added). Because the apparatus is adapted for placement *in-vivo* of a plant or proximate thereto, there are structural attributes provided to the apparatus that one skilled in the art would recognize. Therefore, the recitation of this limitation within claim 1 does add structure to the claimed invention.

In order for the Eckhouse reference to anticipate the claimed invention of claim 1, the Eckhouse reference must teach every element of claim 1. As the Final Office Action states, "the Eckhouse reference... is simply silent with respect to the use of the device to treat a plant." (page 5, lines 2-4). Because the functional language purported by the Final Office Action as mere use of the device conveys structural limitations to one skilled in the art, the Eckhouse reference fails to teach every element of claim 1. Consequently, the Eckhouse reference also does not teach every element of claim 2 which depends from claim 1.

B. Functional language of claim 11 constitutes a structural limitation which is not taught in the Eckhouse reference, and the Eckhouse reference is not inherently capable of being located in proximity to the tympanic membrane.

The Final Office Action asserts that the functional language of claim 11 does not recite a structural limitation but rather only a proposed use for the device of claim 11. However, the functional language of claim 11 does impart structural limitations to one skilled in the art and therefore is a structural limitation.

The Final Office Action also asserts that the device taught in the Eckhouse reference is inherently capable of being located in proximity to the tympanic membrane of a subject. However, the Eckhouse reference provides no evidence that the disclosed device can perform the function of the apparatus claimed in claim 11.

1. Functional language of claim 11 constitutes a structural limitation which is not taught in the Eckhouse reference.

Appellants assert that the functional language of claim 11 reciting "at least part of said apparatus is adapted for placement proximate to said tympanic membrane of said animal" recites a structural limitation to the claimed invention. The Final Office Action stated, "claim 11 recites a device that is "adapted for placement proximate to said tympanic membrane of said animal. Again, this recitation defines no particular structure and is only suggestive of how the device may be used." (page 5, lines 10-12).

Based on the sections of the MPEP cited previously, Appellants assert that the above mentioned limitation of claim 11 does in fact add structural limitations to the claim in that the

apparatus is "**adapted** for placement proximate to said tympanic membrane of said animal." (See claim 11)(emphasis added). Because the apparatus is adapted for placement proximate to said tympanic membrane, there are structural attributes provided to the apparatus that one skilled in the art would recognize.

Moreover, as the MPEP § 2173.05(g) states, functional limitations must be evaluated in the context in which they are used. Claim 11 does not expressly provide for the treatment of the tympanic membrane; however, it does expressly provide that the intensity of the electromagnetic radiation is such that erythema on the tympanic membrane is minimized. Because erythema is an effect of electromagnetic radiation, as mentioned previously in footnote 1, the language of claim 11 implies that the tympanic membrane is subjected to electromagnetic radiation of an intensity which minimizes erythema on the tympanic membrane. Thus, the apparatus is attributed with structural limitations which allow the tympanic membrane to be exposed to electromagnetic radiation of some intensity. Therefore, the recitation of this functional limitation in claim 11 does add structure to the claimed invention of claim 11.

In order for the Eckhouse reference to anticipate the claimed invention of claim 11, the Eckhouse reference must teach every element of claim 11. As the Final Office Action states, "the Eckhouse reference... is silent regarding the treatment of the tympanic membrane of a subject." (page 5, lines 13-14). Because the functional language purported by the Final Office Action as mere use of the device conveys structural limitations to one skilled in the art, the Eckhouse reference fails to teach every element of claim 11.

2. The device taught in the Eckhouse reference is not inherently capable of being located in proximity to a tympanic membrane.

Appellants assert that the device in the Eckhouse reference is not inherently capable of being located in proximity to a tympanic membrane as claimed in claim 11. The Final Office Action states:

> The examiner maintains that while the Eckhouse reference is silent regarding the treatment of the tympanic membrane of a subject, the device is inherently capable of being located in proximity to the tympanic membrane and therefore meets the structural limitations of the claims.

> Claim 11, as discussed above, merely requires the device to be capable of being located in proximity to a tympanic membrane. The Eckhouse device is clearly "adapted" to be located in proximity to a tympanic membrane. The method steps of claim 11 do not recite that the device is actually located near or used to treat a tympanic membrane. As such, Eckhouse is deemed to meet the limitations of claim 11 in that use.

(page 5, lines 12-22; page 6, line 1).

Regarding inherency, a gap in a cited reference may be filled by extrinsic evidence, but such evidence must be necessarily present in the thing described in the reference. *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). However, inherency may not be established on mere probabilities or possibilities. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). Simply because "a certain thing may result from a given set of circumstances", is not sufficient to establish inherency. *See Id.*

The Final Office Action states that because claim 11 does not expressly provide for the treatment of the tympanic membrane, that the Eckhouse reference meets the limitations of claim 11. However, as stated previously, the apparatus of claim 11 provides "electromagnetic radiation having an intensity sufficient to achieve meaningful suppression in acute otitis media while minimizing erythema on the tympanic membrane of said animal." Because the intensity of the electromagnetic radiation is used to minimize erythema on the tympanic membrane, the tympanic membrane according to claim 11 is subject to electromagnetic radiation from the apparatus of claim 11.

The Eckhouse reference teaches the use of electromagnetic radiation in the treatment of skin disorders primarily. (col. 8, lines 56-57). Alternatively, the Eckhouse reference teaches the use of a flashlamp in invasive procedures such as lithotripsy or the removal of blood vessel blockage. (col. 8, lines 57-60). The Eckhouse reference offers evidence of treating skin ailments but offers none with respect to the treatment of acute otitis media, or being proximate to a tympanic membrane such that the tympanic membrane would be subjected to electromagnetic radiation. Therefore, the Eckhouse reference does not inherently teach all of the claim elements of claim 11. Specifically, the Eckhouse reference does not teach a device which is inherently capable of being located in proximity to the tympanic membrane of an animal as recited in part in claim 11.

Because the Eckshouse reference does not teach all of the claim elements of claim 11, claim 11 is not anticipated by the Eckhouse reference. Consequently, the Eckhouse reference

does not teach all of the claim limitations of claims 3-10, 12, and 13 which depend from claim 11. Thus, claims 3-10, 12, and 13 are also not anticipated by the Eckhouse reference.

II. The Final Office Action does not properly reject claim 10 under 35 U.S.C. § 103 over Eckhouse in view of Talmore because the Final Office Action fails to teach all of the claim limitations of claim 10 and therefore does not establish a *prima facie* case of obviousness.

The Final Office Action rejects claim 10 under 35 U.S.C. § 103 as obvious over Eckhouse in view of Talmore. However, in order to establish a *prima facie* case of obviousness, three requirements must be met. MPEP §2143. First, there must be some suggestion or motivation, either in the cited references or in the knowledge generally available to one ordinarily skilled in the art, to modify the reference. *Id.* Second, there must be some reasonable expectation of success. *Id.* Third, the cited references must teach or suggest all of the claim limitations. *Id.* Also the United States Code provides "[a] claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers." 35 U.S.C. § 112 (4th paragraph). The Final Office Action fails to establish a *prima facie* case of obviousness because the combination of references fails to teach or suggest all of the claim limitations of the claimed invention.

The Final Office Action asserts that the Talmore reference teaches "a light treatment device for the treatment of psoriasis, similar to the Eckhouse skin treatment device. In particular, Talmore teaches the use of flashlamps to treat psoriasis, as well as additional skin conditions such as skin fungus as disclosed in column 4, lines 62-68 of the Talmore patent."

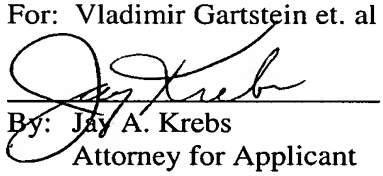
However, claim 10 depends from claim 11, and as previously asserted, the functional language of claim 11 recites a structural limitation of the present invention. While the Talmore reference may teach some of the claim limitations that the Eckhouse reference is lacking, i.e. the treatment of pathogens and fungi, the Talmore reference fails to teach or suggest the claim limitations which distinguish the claimed invention of claim 11 over the Eckhouse reference. Namely, the Talmore reference fails to teach or suggest that the apparatus is "adapted for placement proximate to said tympanic membrane of said animal," as recited, in part, in claim 11. Because claim 10 depends from claim 11, the cited combination fails to teach or suggest all of the claim limitations of the invention of claim 10.

So, the Office Action fails to establish a *prima facie* case of obviousness, and therefore, Applicants assert that claim 10 is nonobvious over the cited combination.

SUMMARY

None of Claims 1-13 has been properly rejected under 35 U.S.C. § 102 or § 103 in light of the reasoning and analysis given in the Final Office Action. In light of all of the analysis and discussion provided above, Appellants respectfully request the Honorable Board of Patent Appeals and Interferences to reverse the rejections of Claims 1-13 and to remand the application with instructions that these claims be allowed over the cited art.

Respectfully submitted,
For: Vladimir Gartstein et. al



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June 1, 2004
Cincinnati, OH

APPENDIX
CLAIMS

1. An apparatus for the meaningful suppression of the growth potential of a pathogen *in-vivo*, said apparatus comprising an electromagnetic radiation source capable of providing broad-spectrum electromagnetic radiation, wherein said broad-spectrum electromagnetic radiation includes wavelengths of from about 190 nm to about 1200 nm, said broad-spectrum electromagnetic radiation having an intensity sufficient to achieve meaningful suppression in said growth potential of said pathogen *in-vivo* and wherein at least part of said apparatus is adapted for placement proximate to the *in-vivo* location of said pathogen, wherein said *in-vivo* location of said pathogen is a plant or parts thereof.

2. The apparatus according to Claim 1 wherein said electromagnetic radiation is a pulsed broad-spectrum electromagnetic radiation and said electromagnetic radiation is pulsed from about 1 to about 1000 times and for a duration of each pulse from about 1 microsecond to about 500 milliseconds.

3. The apparatus according to Claim 11 wherein said electromagnetic radiation source is selected from the group consisting of halogen lamps, xenon lamps, halogen enhanced UV lamps, xenon flash lamps, mercury xenon lamps, deuterium lamps, vacuum UV lamps, mercury lamps, lasers and combinations thereof.

4. The apparatus according to Claim 11 wherein said broad-spectrum electromagnetic radiation is a continuous spectrum.

5. The apparatus according to Claim 11 wherein said broad-spectrum electromagnetic radiation is a combination of at least two discrete spectra.

6. The apparatus according to Claim 11 wherein said apparatus comprises a controller, said controller managing the duration and intensity of said electromagnetic radiation source.

7. The apparatus according to Claim 11 wherein said apparatus is hand held.

8. The apparatus according to Claim 6 wherein said controller is manageable from a location remote from the apparatus via a data link, said data link being operatively connected to said controller.

9. The apparatus according to Claim 11 wherein said broad-spectrum electromagnetic radiation has an intensity from about 0.01 J/cm^2 to about 1 J/cm^2.

10. A method for achieving the meaningful suppression of the growth potential of a pathogen in a living organism comprising applying a broad-spectrum electromagnetic radiation from an apparatus according to Claim 11 to said living organism at the locus of said pathogen in said living organism

11. An apparatus for the treatment of acute otitis media in an animal comprising an electromagnetic radiation source capable of providing broad-spectrum electromagnetic radiation, wherein said broad-spectrum electromagnetic radiation has wavelengths of from about 190 nm to about 1200 nm, said broad-spectrum electromagnetic radiation having an intensity sufficient to achieve meaningful suppression in acute otitis media while minimizing erythema on the tympanic membrane of said animal; wherein at least part of said apparatus is adapted for placement proximate to said tympanic membrane of said animal.

12. The apparatus according to Claim 11 wherein said electromagnetic radiation is a pulsed broad-spectrum electromagnetic radiation and said electromagnetic radiation is pulsed from about 1 to about 1000 times and for a duration of each pulse from about 1 microsecond to about 500 milliseconds.

13. The apparatus according to Claim 11 wherein said apparatus comprises a power source.